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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,062	03/05/2002	Li-Lan H. Chen	366325-524	8011

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/091,062

Applicant(s)

CHEN ET AL.

Examiner

Frank I Choi

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 19-51 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 19-51 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Appendix B*.

DETAILED ACTION

Priority

Applicant claims priority as a continuation of US Pat. App. 09/619,899. However, the present application while reciting some subject matter similar to the above mentioned application does not appear to be a continuation since the specifications do not appear to recite the same material. For example, US Pat. App. 09/619,899 recites a definition for "solid dispersion" which is not recited in the present application and the number of drawings is different between the two applications. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application.

Specification

Claims 9,30 are objected to because of the following informalities:

Claims 9, 35, line 2 of each, "polysaccharade" should be "polysaccharide".

Claim 30, line 10, "dissolution time on" should be "dissolution time of".

Claim 48, line 1 "dissintegration" should be "disintegration".

Claim 49 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 30 on which Claim 49 dependent already contains a limitation in which the active agent is encapsulated by a polymer which is chemically or physically distinct from the hydrocolloid.

There is no claim 18.

There are two claims numbered 24 and claim 26 is dependent on claim 24.

The disclosure is objected to because of the following informalities:

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Pg. 25, lines 1, 2, "Sildaneditl" should be "Sildenafil", "Sildanefil" should be "Sildenafil".

Pg. 6, line 15, Figure 6 and Pg. 25, line 2, "Viagra" should be followed by "®".

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claims 27, 30, 49 recite a limitation wherein the active agent is encapsulated by a polymer which is chemically or physically distinct from the hydrocolloid. However, the specification does not appear to contain this limitation and mentions encapsulation only in relation to dissolution properties (See Specification, pg. 4, lines 9,10, pg. 9, lines 5-8).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17, 19-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-17, 20-43, 45-51 contain the phrase "effective dose of a sexual dysfunction active agent", however, the Specification (other than sildenafil citrate) does not appear to define what would constitute a sexual dysfunction active agent or effective dose thereof. As such, it does not appear that one of ordinary skill in the art would be reasonable apprised of the scope of the invention.

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Claims 7, 33 recite the phrase “a hydration rate in 24 hours of 5-20% at 75% humidity at room temperature” which renders the claim indefinite as it is uncertain what the percent relates to.

Claims 28, 50 recite the phrase “wherein the dosage unit comprises at least two active agents” which lacks antecedent basis as the independent claim appears to indicate that the composition contains a single sexual dysfunction active agent.

Claims 29, 51 recite the phrase “concentration of up to 50%” which renders the claims indefinite as there are no units, i.e. volume or mass.

Claims 27, 30, 49 recite a limitation wherein the active agent is encapsulated by a polymer which is chemically or physically distinct from the hydrocolloid. However, the specification does not appear to define what would constitute “chemically or physically distinct” and mentions encapsulation only in relation to dissolution properties (See Specification, pg. 4, lines 9, 10, pg. 9, lines 5-8). As such, it appears that one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Examiner notes that the measurement of the properties of the film is based on protocols which are described in the Annual Book of ASTM Standards (1995) and “Dry tack” is measured using Texture analyzers, model TA.XT2i. Examiner is uncertain whether these tests or protocols are recognizable commercial standards or otherwise can be standardized such that one of ordinary skill in the art would be able to determine the scope of the claims herein. As such, Examiner requests copies of the relevant ASTM and relevant manufacturer’s specs of the Texture Analyzer, model TA.XT2i, such that they may be readily available should the present Application be issued as a patent.

Double Patenting

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17, 19-51 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/434,878. Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending Application claims a film containing sildenafil citrate, hydrocolloid, and adhesion enhancer, such as starch graft copolymer, in which the active agent can be encapsulated by a polymer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

October 10, 2002


JOHN PAK
PRIMARY EXAMINER
GROUP 1600

